CDC VISI Industry Forum
Meeting Minutes from April 26, 2001

Participating Organizations

- Aventis Pasteur
- Chiron
- Glaxo Smith Kline
- Merck
- Wyeth-Lederle

Meeting Objective

- Review and discuss the CDC VISI proposed guidelines - concentrating on technical feasibility, economics, and alternatives.
- Provide an industry response to and recommendations for the CDC VISI guidelines.

CDC Objective

- Improve the compliance and accuracy associated with vaccine information entry. Automate the process to limit the opportunity for human error in the process of recording information.
- Provide for the capability to initiate a National database for all patients receiving vaccines.

Review of CDC VISI Proposed Guideline

- See summary attachment based on CDC VISI draft guidelines as of April 2001 - www.cdc.gov/nip/visi/prototypes.htm.

Industry Position

- Overall, the industry supports the CDC VISI objective of improving the transfer of critical information from the primary container to appropriate records.
- The position on the individual parts of the guideline is as follows:
  - There is no support for the "Vaccine Facts" sidebar.
    - The FDA is currently proposing that most of this information be incorporated into the product insert. The industry is currently planning to comply.
    - The use of the "Vaccine Facts" sidebar does not support the overall VISI objective to improve the transfer of information.
    - The cartons are generally disposed upon receipt and storage of the vaccine.
  - The use of the NDC number or a standard number for the data base is generally accepted. Most organizations are global. To fully utilize the data base, consideration should be given to methods for a global number data base.
  - Abbreviations are currently in use for vaccine identification. The industry supports using currently approved abbreviations and the expansion of the use of abbreviations. The limit to three characters for the abbreviations is not supported.
  - There is no issue with the concept of providing a method for the transfer of data from the primary container to other documents. However, the industry takes issue with the selection of the RSS code for the detachable labels, the UCC/EAN-14 code for the carton and multiple detachable labels.
    - There is insufficient data on customer user requirements and usage.
    - There are significant technical issues with the implementation of the recommendations.

Economic and Timing Considerations

- The economic impact of the implementation of the CDC guidelines is significant (Millions). A cost benefit analysis would helpful in justifying the expenditure.

- It is estimated that it could take from three to seven years to fully implement the proposed changes.
- It is critical to determine the technology and plan of action to limit investments.

Recommendations

- Adopt a three phased approach to implement methods for improved data transfer.
  - Phase 1; Implement a single detachable label for single dose presentations that includes only the human readable required information (Generic name, Lot #, and Manufacturer). Move to multidose presentations after single dose is completed.
  - Phase 2; Form an industry working group to meet with government agencies and user groups. The group to explore the available technologies, make recommendations based on cost/benefit and appropriate technology and develop a fully automatic data transfer system.
  - Phase 3; Implement fully automatic data transfer system
- Initiate a working group to meet with appropriate agencies (FDA, European, BOB, etc.) to streamline review and approve guidelines for NDC or other data base. Include representatives from each company, CDC, FDA, European Agencies, BOB.

Next Steps

- Provide minutes of the meeting from April 26, 2001. (R. Filipski by May 4, 2001)
- Forum participants to review and comment on minutes by May 11, 2001. (All Participants)
- Provide CDC with final minutes of the Industry Forum minutes from April 26, 2001. (R. Filipski by May 15, 2001)
- Form a review group consisting of the current industry forum members plus representatives from Medeva and Parkedale (King Pharmaceutical).
  - Supply required system specifications for coordination into one specification by May 15, 2001. (All Participants)

- Provide specifications to selected vendors (Data Matrix, UCC, Safety Syringes, Inc.) in face-to-face meeting Friday June 15, 2001 at Wyeth-Lederle.
- Vendor presentations to the review group on Friday July 13, 2001 at Glaxo Smith Kline.

- Form a review group consisting of industry and agency representatives to review the NDC number and abbreviation data and make recommendations.